UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

April 16, 2015

DP BARCODE: 423297/425012

MRID: 49468300, 49468301, 49468302, and 49468303; and 49469600, 49469601, 49463602, and 49469603

SUBJECT: Seaquantum Ultra SP Light Red

REG. NO.: 2568-RNG

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
025601	1317-39-1	Cuprous Oxide
088001	14915-37-8	Copper Pyrithione

TEST LAB:

SUBMITTER: ST Technical Associates, LLC

GUIDELINE: Group A and B Product Chemistry

ORGANIZATION: AD\PSB\CTT

REVIEWER: Lynette T. Umez-Eronini

APPROVED BY: Karen P. Hicks

APPROVED DATE: April 15, 015

COMMENT: Studies were submitted under two different DP barcodes (see above). The chemistry review herein is referenced under the two DP barcodes. This product is for non-food use.

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April 15, 2015

MEMORANDUM

SUBJECT: Product Name:	Product Chemistry Review for EPA Reg. 2568-RNG Seaquantum Ultra SP Light Red DP Barcode: 423297/425012
DATE DUE:	May 7, 2015
FROM:	Lynette T. Umez-Eronini, Chemist Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
THRU:	Karen Hicks, Team Leader Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
TO:	Elizabeth Watkins PM #33/Karen Leavy Regulatory Management Branch I Antimicrobials Division (7510P)
Applicant:	Jotun Paints Inc.
CODE:	A550 New Product; Non-Fast Track

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
COPPER OXIDE	48.20*
COPPER PYRITHIONE	2.23
INERT INGREDIENTS:	49.57**
Total:	100.00

*METALLIC COPPER EQUIVAONE: 43.2%
**CONTAINS PETROLIEM DISTILLATES, XYLENE, OR RANGE AROMATIC SOLVENTS.

BACKGROUND:

The consultant, ST Technical Associates LLC, on behalf of the registrant, Jontun has submitted an application for registration of a new non-integrated end-use product called Seaquantum Ultra SP Light Red. The product is an antifoulant paint for use on hulls of seagoing vessels.

The following documents were reviewed:

1. Cover letter (from the registrant to EPA), 9/11/2014.
2. Application for registration, 10/20/2014.
3. Basic and Alternate 1 Confidential Statements of Formula (CSFs), 9/2/2014.
4. Draft label, pin-punched 9/16/2014.
5. Data Matrix, 9/9/2014, 2 pages.
6. Summary of the Physical/Chemical Properties (form 8570-36), 9/4/2014.
7. Self-Certification Statement for the Physical/Chemical Properties (PR Notice 89-1) (form 8570-36), 9/4/2014.
8. Updated Basic and Alternate 1 CSFs, April 8, 2015.
9.

49468300	Jotun Paints, Inc. (2014) Submission of Product Chemistry, Toxicity and Environmental Fate Data in Support of the Application for Registration of SeaQuantum Ultra SP Light Red. Transmittal of 11 Studies.
49468301	Branch, C.; Renthrope, J.; Turley, P. (2014) Product Chemistry of SeaQuantum Ultra SP Light Red- Group A. Project Number: STTA/SR02/14J. Unpublished study prepared by Jotun Paints, Inc. 64p.
49468302	Gravelle, W. (2014) Enforcement Analytical Method for the Determination of Cuprous Oxide by Atomic Absorption Spectrophotometry and Copper Pyrithione by High Pressure liquid Chromatography. Project Number: 36579/EAM. Unpublished study prepared by Product Safety Laboratories. 15p.
49468303	Turley, P. (2014) Product Chemistry of SeaQuantum Ultra SP Light Red- Group B: Summary of Physical/Chemical Properties. Project Number: STTA/SR04/2014J, 36579, 36580. Unpublished study prepared by Jotun Paints, Inc. and Product Safety Laboratories. 8p.
49469600	Arch Chemicals, Inc. (2014) Submission of Product Chemistry Data in Support of the Application for Registration of Seaquantum Ultra SP Light Red. Transmittal of 3 Studies. Same as cover letter from Lonza, 9/14/2014.
49469601	Shalvoy, R. (2014) Physical and Chemical Properties of CuPT Paste. Project Number: 263/14B10CUPT. Unpublished study prepared by Lonza Microbial Control. 45p.
49469602	Hull, L. (2014) Accelerated Storage Stability and Corrosion Characteristics of Copper Pyrithione Paste. Project Number: 272/14B10CUPT. Unpublished study prepared by Lonza

	Microbial Control. 31p.
49469603	Jenkins, L. (2014) Copper Omadine Paste: Product Identity, Manufacturing Process, Impurity Discussion and Certified Limits. Project Number: 201401LJ. Unpublished study prepared by Lonza, Inc. 63p.

FINDINGS:

1. Basic and Alternate CSFs, 9/2/2014 are obsolete and are superseded by Basic and Alternate CSFs, 4/8/2015.
2. The nominal concentration of each active ingredient on the Basic and Alternate CSFs, 4/8/2015 is consistent with the label.
3. All ingredients in the formulation are approved for non-food use in pesticide formulations.
4. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 49468301, 49468302, and 49468303 and Table A below). Note: the certificate of analysis for this product is waived by the storage stability study that was provided for product.
5. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 49468303 and Table B below).

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Basic and Alternate 1 CSFs, April 8, 2015 to be acceptable. Also Group A and B Product Chemistry data requirements have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [X] No [ ]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]
(They should read as follows in f below.)

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
CUPROUS OXIDE	48.20	46.8	49.06
COPPER PYRITHIONE	2.23	2.12	2.34

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [X] No [ ]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [X] No [ ] Not applicable [ ]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [X] No [ ] Not applicable [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49468301
830.1600 Description of Materials	A	49468301
830.1620 Production Process[2]		
830.1650 Formulation Process[3]	A	49468301
830.1670 Formation of Impurities[4]		
830.1700 Preliminary Analysis[5]		
830.1750 Certified Limits[6]	A	49468301
830.1800 Enforcement Analytical Method[7]	A	49468302 and 49469603
830.1900 Submittal of Samples	*[Sample are available upon request]*	49468301

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Viscous liquid	49468303
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Product does not contain components with oxidizing and reducing groups.	49468303
830.6315 Flammability/ Flame Extension	A	Flash point: 21.5±0.5°C (70.7±0.9°F), Pensky-Martens closed cup.	49468303
830.6316 Explodability	A	N/A, the product does not contain reactive groups that would be explosive.	
830.6317 Storage Stability **(Accelerated)**	A	Time 0: Cu_2O=49.3±0.2%(AA), CuPT=2.30±0.03% HPLC) After 14 days, 54C: Cu_2O=49.4±1.1%(AA), CuPT=2.17±0.01% HPLC) No weight or other changes were observed.	49468303
830.6319 Miscibility[1]	A	N/A, end-use product is not an emulsifiable liquid and is not diluted before use.	49468303
830.6320 Corrosion Characteristics (**Accelerated**)	A	No signs of deformation, cracking, pitting, rusting or corrosion of containers were observed during test period.	49468303
830.6321 Dielectric Breakdown Voltage	A	N/A, end-use product is not used around electrical equipment.	49468303
830.7000 pH[2]	A	N/A, end-use product is not used around electrical equipment.	49468303
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	106.2 ± 2.1 Kreb units at 25°C., ASTM D562-10.	49468303
830.7200 Melting Point/Melting Range	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	1.974±0.002 at 20°C., ASTM D891-95 (specific gravity bottle)	49468303
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
Note: Value or Qualitative Description for Miscibility inadvertently stated description for Dielectric Breakdown voltage in MRID 49468303. Phone call (4/14/2015) made to the consultant corrected the description.

[2]If product is dispersible with water